UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	**OIA-308 WORKSHEET:** Admin Pre-Review		
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The purpose of this worksheet is to provide support for Office of IRB Administration (OIA) staff conducting pre-review of submission materials. This worksheet, or equivalent, is to be used. This worksheet is not required to be completed or retained.

1 INITIAL REVIEW and AMENDMENT (when the amendment affects one of the following)

- ☐ Determine the regulations that apply to the human research and select these in the "regulatory oversight" section of *OIA-401 CHECKLIST: Pre-Review*, or equivalent.
- ☐ Determine whether the principal investigator is restricted. If so, note in the "restrictions" section of *OIA-401 CHECKLIST: Pre-Review*, or equivalent.
- ☐ Determine risk level of research and note in the "risk level" section of *OIA-401 CHECKLIST: Pre-Review*, or equivalent.
- ☐ Determine that the type of research is conducted or overseen by the institution.
- ☐ Determine that the type of research is not reviewed by an external IRB.
- ☐ If the research involves the use of a drug or biologic use the *OIA-306 WORKSHEET: Drugs*, or equivalent.
- ☐ If the research involves the use of a device [including a humanitarian use device (HUD)] use the *OIA-307 WORKSHEET: Devices*, or equivalent.
- ☐ Determine whether any special determinations are required. If so, note in the "special determinations" section of *OIA-401 CHECKLIST: Pre-Review*, or equivalent.
- ☐ Determine which protocol tracking item applies. Note in the "protocol tracking" section of *OIA-401 CHECKLIST: Pre-Review*, or equivalent.
- ☐ If a HIPAA waiver of authorization is required, review using *OIA-441 CHECKLIST: HIPAA Waiver of Authorization*, or equivalent.

Note any missing materials in the "missing materials" section of *OIA-401 CHECKLIST: Pre-Review*, or equivalent:

- ☐ Investigator/sponsor protocol
- ☐ Point-by-point response (following modifications required)
- ☐ Evaluation of any related financial interest
- ☐ Application form selections/sections
- ☐ Materials meant to be seen or heard by subjects
- ☐ Consent documents and scripts
- ☐ Investigator brochure for investigational drug/biologic
- ☐ Investigational new drug (IND) validation for investigational drug
- ☐ Package inserts for marketed drugs/biologics
- ☐ Product information/instructions for use for medical devices
- ☐ Protocol review and monitoring committee (PRMC) approval/exemption for oncology studies
- ☐ *OIA-509 TEMPLATE QUESTIONNAIRE: UCSD Local Context Questionnaire*, or equivalent

Note missing/inappropriately answered investigator-initiated protocol sections in the "missing materials" section of *OIA-401 CHECKLIST: Pre-Review*, or equivalent:

Interventional Protocol:

- ☐ Protocol summary
- ☐ Introduction
- ☐ Objectives and endpoints
- ☐ Study design
- ☐ Study population
- ☐ Study intervention
- ☐ Study intervention discontinuation and participant discontinuation/withdrawal
- ☐ Study assessments and procedures
- ☐ Statistical considerations
- ☐ Supporting documentation and operational considerations
- ☐ References

Non-Interventional Protocol:

- ☐ Study title
- ☐ Principal investigator
- ☐ Study rationale
- ☐ Specific aims/hypotheses
- ☐ Background and significance
- ☐ Research design and methods
- ☐ Research participants
- ☐ Recruitment
- ☐ Informed consent
- ☐ Banking of information/biospecimens for future uses OR identifiable private information about research participants
- ☐ Minimization of risk
- ☐ Privileges/certifications/licenses and research team responsibilities OR qualifications, training, cultural literacy, and research team responsibilities
- ☐ References
- ☐ Bibliography

Note any of the following in the "final contingencies" section of *OIA-401 CHECKLIST: Pre-Review*, or equivalent:

- ☐ Conflict of interest disclosure is required but not present
- ☐ An IND is required and there is no IND
- ☐ An IND is required and there is insufficient documentation
- ☐ An Investigational device exemption (IDE)/Humanitarian device exemption (HDE) is required and there is no IDE/HDE
- ☐ An IDE/HDE is required and there is insufficient documentation
- ☐ There are inadequate provisions to control the drug(s)/biologic(s)
- ☐ There are inadequate provisions to control the device(s)
- ☐ External site for which we are IRB of record receiving federal funds from the institution does not have a federalwide assurance (FWA)
- ☐ The research involves adults unable to consent and statements by the investigator and local context regarding which individuals are legally authorized representatives do not match.
- ☐ The research involves adults unable to consent and statements by the investigator regarding provisions for ongoing consent are inadequate.
- ☐ The research involves children and statements by the investigator and local context regarding which persons are considered children do not match.

2	**CONTINUING REVIEW or AMENDMENT**
☐	Determine whether any new reportable event at a site under UCSD IRB purview has been disclosed (for example, an unanticipated problem involving risks to subjects or others/unanticipated problem report). If so, direct the researchers to submit a reportable event and then follow *OIA-024 SOP: Reportable Events*.
☐	Note incomplete continuing review form in the "missing materials" section.
3	**STUDY CLOSURE**
☐	Confirm that the research meets the criteria for closure and note in the study closure section of *OIA-401 CHECKLIST: Pre-Review*, or equivalent.
☐	Determine whether any new information has been provided, e.g., a new risk. If so, follow *OIA-024 SOP: Reportable Events*.